K000776

FEB - 7 2001

SUMMARY OF SAFETY AND EFFECTIVENESS (K000776)

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Date Summary Prepared: January 31, 2001

Trade Name of Device: Medtronic DLP Arterial Cannulae, modified with 3D Tip (24 French)

Classification Name of Device: Cardiopulmonary bypass vascular cannula
Class II at 21 CFR 870.4210

Predicate Substantially Equivalent Device: Medtronic DLP Arterial Cannulae, Class II at CFR 870.4210, Straight Tip and Curved Tip Models (K840001 and K8400002)

Description of Device: The Medtronic DLP Arterial Cannulae with 3D Tip (24 French) represents modified versions of existing Medtronic DLP Arterial Cannulae. The proposed change involves the incorporation of a baffled tip designed into the cannula. This baffled tip imparts a more diffuse pattern of blood flow exiting from the cannula tip than exists with the existing open tip cannula design

Intended Use: The cannulae are intended for the perfusion of the ascending aorta during cardiopulmonary bypass surgery.

Comparison to Existing Predicate Device: The Medtronic DLP Arterial Cannulae with 3D Tip (24 French) are substantially equivalent to existing Medtronic DLP Arterial Cannulae. The existing cannulae have been modified to include a baffled tip, which features side exit holes and scoop-shaped exit ports on the outside of the tip surface. The indications for use for both the existing and modified devices are identical, and the addition of a baffled tip feature does not represent a change in the fundamental scientific technology of the device.

Summary of Non-Clinical Performance Data: The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the Medtronic DLP Arterial Cannulae with 3D Tip (24 French) does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed arterial cannulae. The *in vitro* bench testing included:

Assessment of the fluid flow resistance
Assessment of the dynamic hemolytic properties

Conclusion: The results of the non-clinical tests support an assertion that the Medtronic DLP Arterial Cannula modified with a 3D Tip (24 French) is as safe and effective as the existing Medtronic DLP Arterial Cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2001

Medtronic Cardiac Surgical Products
c/o Ms. Debra Kridner, Director
Regulatory and Clinical Affairs
Medtronic Perfusion Systems
620 Watson, SW
Grand Rapids, MI 49504

Re: K000776
Trade Name: Medtronic DLP Arterial Cannulae with 3D Tip
Regulatory Class: II (two)
Product Code: DWF
Dated: December 12, 2000
Received: December 13, 2000

Dear Ms. Kridner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510K – K000776

Device Name: Medtronic DLP Arterial Cannulae with 3D Tip (24 French)

Indications for Use: These cannulae are intended for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The Counter Use ____

(Per 21 CFR 801.109

2-6-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K000776